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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,010	01/22/2004	Eugene J. Alexander	3104/109	8938

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
01/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,010	ALEXANDER ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10,15,18-22,55-61,66-71,85,86 and 94-227* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, and 94-227* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, and 94-227 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the preamble recites “determining a therapy”, however, it does not appear that any type of therapy is determined. In claims 10, 153, and 190, the therapy is identified by, "wherein said therapy is an implant". However, it is unclear how an implant can be considered therapy. For purposes of examination, this is interpreted as meaning that the implant contains something which acts as a therapy. Also in claim 1, it is unclear what size thickness “a thickness similar to that of normal articular cartilage adjacent to diseased articular cartilage” refers to. This is not a standard description of a size, and

as each person will have different thicknesses of their cartilage, this size may vary considerably. The size of the normal cartilage may also vary based on the progression of the diseased cartilage.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, and 94-227 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). *See* Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 10, 15, 18-19, 21-22, 55-58, 60-61, 66-71, 85-86, 94-156, 158-194, and 196-227 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp et al. (US 5682886) in view of Aouni-Ateshian et al. (US 6161080), Paul et al. (US 5320102), and Goldberg et al. (US 6835377).

Delp et al. show a system for joint replacement surgery. The system processes medical image data to build a 3D computer model of the patient's leg, and align, size, and place a prosthetic component (column 8, lines 5-31). The three-dimensional geometry of the joint is analyzed to determine the required dimensions and geometry of the prosthesis. A number of points are selected in the 3D surface reconstruction of the joint and prosthesis (column 9, line 19-column 11, line 5). Selecting points in three-dimensional space in order to develop the proper dimensions and geometry of a three-dimensional object would inherently include determining three non-coplanar points. Points would be selected on the different bones of the joint, such as in the case of a knee joint, the lateral or medial femoral condyle (column 7, lines 38-52). A variety of

different imaging modalities can be used to obtain the data (column 8, lines 32-61). The biomechanical information, such as the biomechanical axes, is obtained (column 11, lines 49-59) and used when designing the model, as well as anatomical information such as anatomical landmarks (column 11, lines 25-27). When planning the design of the prothesis, the contact surfaces are accounted for as well (column 14, lines 1-42). By utilizing constraints, both static and dynamic alignment are accounted for, in order to ensure that there is equal contact throughout the range of motion and to prevent the ligaments from being too tight in extension. Estimating for normal gait is an obvious modification, as gait is a typical unconstrained movement, and would be accounted for when ensuring equal contact throughout the range of motion. Delp et al. fail to teach that the cartilage thickness can be reconstructed as well as analyzing degenerative cartilage in the patient, as Delp mainly discusses bone. Also, that the implant can be used as a therapy.

Aouni-Ateshian et al. disclose a method of generating a three-dimensional representation of one or more anatomical joints. Aouni-Ateshian et al. teach that cartilage topography and thickness can be reconstructed, and geometric data needed for a model can be obtained (column 37, line 65-column 8, line 25).

When designing a model to analyze an object, it is typical to design the model as close to the real object as possible, in order to accurately analyze what would happen to the real object. Therefore, it is obvious that the physical model would reflect the patient's anatomy, such as the geometry and thickness of the normal and diseased cartilage, and the inner and outer surfaces, and the subchondral bone.

Paul et al. disclose a method of treating a human with diseased cartilage in a joint. Pault et al. teach a method of treating a human with diseased cartilage in a joint (abstract), which method comprises: utilizing an MRI scan to generate a cross-sectional electronic image of said joint (column 4, lines 1-55), wherein said image includes both normal and diseased cartilage (column 10, lines 55-65); and utilizing information from said image to create a geometric model of an area of diseased cartilage (the MR cartilage image is a model, column 4, lines 55-65), wherein said geometric model is used in selecting a treatment of said diseased cartilage (column 11, lines 35-55); electronically evaluating the image of the joint to determine the thickness or biochemical content (column 4, lines 1-10, and column 5, line 65-column 6, line 5); obtaining a three-dimensional map (the MR cartilage image is a three-dimensional map, column 4, lines 55-65); determining the margins of the diseased cartilage in relation to the normal cartilage based on the thickness or biochemical contents, allowing for the area of diseased cartilage to be calculated (the MRI scan of the joint allows for the total cartilage surface area to be determined, knowledge of the margins of the diseased area will then allow for a calculation of the total area of the joint containing diseased cartilage, column 10, lines 55-65). Also, estimating the change in thickness of a region of the cartilage over time to determine a change in thickness between a first time and a second time, to determine the amount of degeneration in the cartilage (column 11, lines 5-55); the therapy includes an agent that stimulates repair of diseased tissue (column 11, lines 45-55); the MRI technique obtains a series of two-dimensional views reconstructed to a three-dimensional image (implicit with MR imaging); the MRI

technique employs gradient or spin echo (column 4, lines 25-40). Data transmission throughout a computer system is well known in the art, any part of the computer can be considered a “site” or the receiving or transmitting device, and the term "located distant" can refer to any distance.

Goldberg et al. disclose a method for repair of degenerative cartilage. Goldberg et al. teach that the therapy can comprise osteotomy or an autologous chondrocyte transplantation (it is well known to perform osteotomy, column 1, lines 40-50, also the method used in the invention uses autologous mesenchymal stem cells supported by a three-dimensional scaffold, which is implanted in the body, column 3, lines 1-25).

Delp et al. mainly discuss the bones when discussing joint replacement surgery, however cartilage must be considered as well when analyzing a patient's joint. It would have been obvious to one of ordinary skill in the art to have applied the same teachings of Delp et al. to the cartilage as well as the bone, as taught by Aouni-Ateshian et al. This will allow for a better implant to be developed for the joint replacement.

It would have been obvious to one of ordinary skill in the art, to analyze the degenerative cartilage in the patient and to have determined a therapy based on the cartilage information as taught by Paul et al., in a joint replacement technique as taught by Delp et al., in order to better develop a proper implant.

It would have been obvious to one of ordinary skill in the art, to have implanted a device as taught by Goldberg et al. in place of the prosthesis implanted by Delp et al. in order to aid in repairing the degenerated cartilage.

Delp et al. analyze the geometry of the joint to determine the required dimensions and geometry of the prosthesis, and in combination with the other references, this would also include the dimensions and geometry of the cartilage, including the cartilage thickness. When designing such an implant, it is of course necessary for it to reflect the proportions of the body part being replaced so that it will fit appropriately within the patient. Therefore, at least a portion of the implant would have thickness similar to that of normal articular cartilage adjacent to diseased articular cartilage.

Claims 20, 59, 157, and 195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp et al. (US 5682886) in view of Aouni-Ateshian et al. (US 6161080), Paul et al. (US 5320102), and Goldberg et al. (US 6835377) as applied to claims 1, 10, 153, and 190 above, and further in view of George, III et al. (US 6175655).

George, III et al. disclose a method for manipulating 3D MRI data to view internal body structure. George, III et al. teach the use of 3D Euclidean distance values in manipulating the 3D MRI data (table of column 8-column 9 shows a variable used which is Euclidean distance between points).

The Euclidean distance is a well known technique to calculate the distance between two points, and could be used when constructing the 3D model.

Response to Arguments

Applicant's arguments filed 10/10/08 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to applicant's arguments that neither Delp, Aouni-Ateshian, nor Paul teach or suggest anything related to the thickness of normal and/or diseased articular cartilage, examiner respectfully disagrees. This is clearly discussed by Paul at least in column 5, line 65-column 6, line 2, as described in the previous rejection.

The supplemental reply filed on 10/16/08 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737